

REMARKS

Claims 1-24 are pending in this application. Claims 15-24 have been withdrawn as being directed to a non-elected invention.

Applicants acknowledge, with appreciation, the Examiner's indication that a proper claim for priority and the certified copy of the priority application filed in Japan have been received, and that the drawings have been accepted.

Objections: Specification

The Examiner has directed attention to the incorrect abbreviation for mass median aerodynamic diameter (MMAD) in Tables 2-5 in the specification. These informalities have been corrected.

The Examiner has improperly assumed that Millipore is a trademark appearing in various paragraphs in the specification. Millipore is actually the name of a company that makes various filter membranes and should not be treated as a trademark itself.

Objections: Claim 6

Claim 6 has been objected to under 37 C.F.R. § 1.75(c) as being an improper dependent claim because it fails to further limit the subject matter of claim 1. Claim 6 has been amended to reduce its scope and avoid the objection. Accordingly, this objection should be withdrawn.

Rejections: § 112, second paragraph

Claims 1-6 and 8-14 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for several reasons that are addressed below.

A. Claims 1-6 and 14 have been rejected as indefinite because the scope of the term "derivative" is unclear. Although applicants disagree with the Examiner's position relative to the context of the claimed invention, these claims have been

amended to recite the derivatives that are exemplified in the present specification at page 26, line 6 to page 27, line 7 of the specification, for example. Accordingly, this rejection should be withdrawn.

B. Claims 2, 4 and 5 have been rejected as allegedly being internally inconsistent because the claim allegedly recite different Markush groups for the hydrophilic stabilizer than what is recited in parent claim 1. We believe that the Office has failed to appreciate that the hydrophilic stabilizers recited in claims 2, 4 and 5 are actually subgenera or species of the hydrophilic stabilizers recited in claim 1 and thus are not only consistent with, but also properly dependent on claim 1. Claims 2-4 have been amended to improve the clarity of those claims, so that the relationship among the Markush groups that are recited in these claims are neither inconsistent nor unclear. Accordingly, this rejection should be withdrawn.

C. Claim 1 also has been rejected as indefinite because the term "fine particle fraction" (FPF) is allegedly not defined in the specification. Applicants disagree. Reference to page 56, line 25 to page 57, line 25, particularly page 57, lines 21 and 22 of the present specification clearly shows that applicants have defined what is meant by "fine particle fraction" according to the present invention. Specifically, the determination is made using a twin impinger apparatus where the fraction that can be expected to be delivered into the lungs is that in stage 2 (the aerodynamic diameter of particles recovered in this fraction is 6.4 microns or less). Accordingly, this term is defined in the present specification and the claims should be read and interpreted in a manner consistent with the specification. Accordingly, this rejection should be withdrawn.

Rejection: § 102 - Yamashita et al.

Claims 1-14 have been rejected under 35 U.S.C. § 102(a) as being anticipated by Yamashita (US 2003/0101995) (now U.S. Patent No. 7,448,379). The Examiner properly recognized that applicants were not able to rely on the foreign priority date of December 13, 2002, as a filing date that avoids the Yamashita et al. published application as a § 102(a) publication without a translation of that document. However, filed concurrently with this reply is a translation of that priority application, along with a certification of its accuracy, to remove Yamashita et al. as a § 102(a) publication. Accordingly, this rejection should be withdrawn.

Claims 1-14 also have been rejected under 35 U.S.C. § 102(e) as being anticipated by Yamashita et al. (US 2003/0101995) (now U.S. Patent No. 7,448,379). We are informed that applicants are preparing a declaration of the type suggested by the Examiner to overcome this rejection, but the signed declaration was not available at the time of filing this reply. The declaration will be filed as soon as it is received.

Rejection: § 103

Claims 1-14 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over JP 61044826 (JP '826), in view of JP 59-181224 (JP '224) and Tober et al. The Office argues that JP '826 teaches the addition of a hydrophobic amino acid to interferon- γ in a freeze-dried composition. JP '826 discloses that the examples of usable amino acids include glycine, alanine, leucine, glutamic acid, aspartic acid and like monoamino aliphatic amino acids. JP '826 does not teach or suggest the combination of hydrophobic amino acids and hydrophilic amino acids as recited in the present claims.

The Office observes that JP '224 teaches the desirability of adding an amino acid, and preferably a hydrophilic amino acid, to a mixture of interferon and human serum albumin to improve the stability of interferon, also in a freeze dried preparation. JP '224 discloses that examples of usable amino acids include arginine, aspartic acid, glutamic acid, histidine, lysine, serine, threonine and like hydrophilic amino acids. However, JP '224 fails to disclose any hydrophobic amino acids and fails to suggest a combination of both hydrophobic and hydrophilic amino acids. Tober et al. merely discloses that IFN- γ is unstable under various conditions.

The prior art does not teach or suggest, nor provide any reason for using both hydrophobic and hydrophilic stabilizers in the same freeze-dried composition. It is further unclear that any combination of the prior art teachings would lead to a composition having the recited disintegration index or having the property of becoming fine particles that would meet the conditions recited in claim 1, for example. Since the prior art fails to establish a prima facie case of obviousness, this rejection should be withdrawn.

Prompt and favorable reconsideration is requested.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Attachments: English Translation of JP 2002-363026